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DE RUEHNE #5366/01 3540547  
ZNR UUUUU ZZH  
R 200547Z DEC 07  
FM AMEMBASSY NEW DELHI  
TO RUEHC/SECSTATE WASHDC 9769  
INFO RUEATRS/DEPT OF TREASURY WASHDC  
RUCPDOG/DEPT OF COMMERCE WASHDC  
RUCNCLS/ALL SOUTH AND CENTRAL ASIA COLLECTIVE  
RUEHCG/AMCONSUL CHENNAI 2104  
RUEHKP/AMCONSUL KARACHI 8369  
RUEHCI/AMCONSUL KOLKATA 1418  
RUEHLH/AMCONSUL LAHORE 4243  
RUEHBI/AMCONSUL MUMBAI 1208  
RUEHPW/AMCONSUL PESHAWAR 4714

UNCLAS SECTION 01 OF 02 NEW DELHI 005366

SIPDIS

SENSITIVE  
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E.O. 12958: N/A

TAGS: [BTIO](#) [ECON](#) [EINV](#) [ETRD](#) [KIPR](#) [IN](#)

SUBJECT: CHEMICALS MINISTRY DETAILS GOI CONSIDERATIONS ON DRUG  
PRICING, DATA PROTECTION

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1. (SBU) Summary: Following a meeting in which Mr. Ranga Iyer of Wyeth Pharmaceuticals expressed concern that the GOI would institute a price-control regime discriminatory against imported drugs, Econoff met with Joint Secretary G. S. Sandhu of the Ministry of Chemicals and Fertilizers (MCF) to discuss the GOI's intentions. Sandhu assured Econoff that the latest draft policy is non-discriminatory and offered details both on the price-control policy and on plans for modifying trade margins for "branded generics." He also told Econoff that the issue of data exclusivity for agricultural chemicals would go before Parliament during its next session but that there has been little progress on the matter of data protection for pharmaceuticals. End summary.

WYETH WORRIED ABOUT PRICE CONTROLS

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2. (SBU) In a meeting with the Economic Counselor on December 12, Mr. Ranga Iyer, Managing Director of Wyeth India and President of the Organization of Pharmaceutical Producers of India, explained that a recent meeting with the MCF had raised concerns about treatment of imported medicines under the proposed price-control regime. Iyer said that while the new system of price controls would apply to domestic drugs only if they are on the List of Essential Medicines (LEM), it would apply to all imported drugs. Maximum sale prices, as Iyer understood it, would never be permitted to exceed 150 percent of the import price but could be set at significantly lower levels on a case-by-case basis.

MCF: NO DISCRIMINATION AGAINST IMPORTS

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3. (SBU) Joint Secretary Sandhu assured Econoff on December 18 that the proposed price-control regime, which has been forwarded from the Cabinet to a Group of Ministers for consideration, would apply only to imported drugs that are off-patent and on the LEM. Sandhu estimated that once all exceptions are granted, approximately 200 of the 354 drugs on the LEM will fall under the new price-control regime, versus 74 under the existing system. Nonetheless, he said, this will still mean only about 32 percent of the total market will fall under formal price controls. Regarding drugs not on the LEM, the MCF also hopes to improve enforcement of the cap on trade margins of 100 percent on the indigenously manufactured "branded generic" segment, where retailers often take margins of 1000 percent or more.

4. (SBU) Patented drugs would remain outside of formal controls

under the new system, but Sandhu said the MCF is interested in negotiating prices for patented, imported drugs as part of the marketing-approval process to keep them accessible. He added, though, that the MCF is sensitive to the difficulties of fairly assessing a pharmaceutical company's expenses in bringing a drug to market. He said the MCF is hoping to develop a system that will consider production costs, international pricing, and local per-capita income, as well as a given drug's efficacy relative to other drugs with similar application. Sandhu explained that the MCF is in discussions with industry stakeholders to develop an equitable system and said the MCF hopes that companies will accept lower prices and pursue profit by seeking greater penetration and volume.

#### LITTLE PROGRESS ON DATA PROTECTION

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15. (SBU) Turning to the issue of data protection, Sandhu indicated that the proposal of three-year protection for agricultural chemicals submitted in the Reddy Report will come before Parliament in the next session. However, he was unaware of any significant progress on protection for pharmaceuticals. The Reddy Report recommended five-year protection for traditional medicines. For modern medicines, the Report proposed a transition period of indefinite length to be followed by five-year protection, but with a number of "safeguards" that would significantly limit the scope of protection. The Ministry of Health is still considering the Reddy committee's proposals for both conventional and traditional medicines and has not made any determinations on eventual policy or even on the length of the transition period for modern medicines. Sandhu said that, for now, the GOI is working to secure data submitted for marketing approval against unauthorized distribution but noted that generic companies can still rely on innovators' data when seeking marketing approval of their own.

#### COMMENT

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16. (SBU) A paper by the Corporate Law Group, which represents a number of pharmaceutical companies in India, explains that the 150-percent cap Iyer mentioned will apply only to those imported drugs on the LEM. Based on that paper and the Joint Secretary's explanation, it appears that not all imported drugs will fall under the formal price-control regime, but Wyeth and other pharmaceutical companies still have reason for concern. It is clear from Econoff's discussion with Sandhu that the MCF, on the dictate of Minister Ram Vilas Paswan, plans to employ a variety of strategies to control prices for both LEM and non-LEM drugs, regardless of whether they are imported or indigenously manufactured.

17. (SBU) The lack of progress on data protection comes as no surprise, since the Ministry of Health was recently made the nodal agency on the issue and has traditionally opposed pharmaceutical data protection. So long as MOH retains the lead on data protection, we expect little progress on this issue.

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